

Medical Affairs Policy & Procedure

Title/Service: PET Scan (Positron Emission Tomography)

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Description:

A PET scan is a three dimensional imaging method used to evaluate the distribution of a radiotracer within the body. The PET scan shows molecular function and activity, which is not available with other imaging methods. The PET scanner detects emitted gamma rays from a radioactive substance given to the individual. A computer uses this information to map an image of the structures where the radioactive substance has accumulated. Differences in the PET images represent differences in structure or organ function. For example, cancerous tissue will absorb more of the substance and appear brighter than normal tissue on the PET images.

Indications of Coverage:

For the purposes of this guideline, diagnosis, staging, restaging, and monitoring is defined as follows:

Diagnosis: The PET is performed prior to a pathology-confirmed diagnosis of a malignancy but the results of the PET may prevent an invasive diagnostic procedure or the PET results will determine the optimal anatomic location for performing an invasive diagnostic procedure.

Staging: The PET is performed after a pathology report has confirmed the presence of a malignancy, but prior to any treatment being performed, when the PET results will determine treatment for the individual and

conventional imaging (for example, computed tomography (CT) or magnetic resonance imaging (MRI)) is inconclusive or where the use of PET would replace multiple conventional imaging studies, when those multiple studies are inadequate for treatment management.

Restaging: The PET is performed after treatment has been completed for detecting residual or recurrent disease or when physical findings or

conventional imaging reports suggest that the disease is progressing, despite current treatment

Monitoring: The PET is performed during treatment to assess the effectiveness of the current treatment

Note: These criteria do not differentiate between the use of PET and PET/CT unless PET/CT is specifically noted.

A PET scan is considered medically necessary for any of the following conditions when **all** of the condition-specific criteria are met:

A. Brain Cancer

1. The PET scan is ordered for diagnosis and staging where metastatic cancer of the brain has been diagnosed, but the primary tumor has not been identified

B. Breast Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging, restaging at the completion of anti-neoplastic and/or radiation treatment, or monitoring response to treatment
3. The PET scan is ordered for metastatic disease restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

C. Coronary Artery Disease

1. Coronary artery disease is known or suspected, the PET will determine which medical or surgical intervention is required, and one of the following is documented:
2. The PET scan is ordered in place of, but not in addition to, a single photon emission computed tomography (SPECT)
3. The PET scan is ordered following an inconclusive SPECT scan (when the results are uninterpretable or do not correlate with the individual's physical findings and other laboratory or imaging results)

D. Cervical Cancer

1. A pathology report confirms the presence of a malignancy

2. The PET scan is ordered for staging (for surgical treatment planning) when conventional imaging is negative or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

E. Colorectal Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings, rising CEA (an elevation or rise in two consecutive tests performed at least one month apart), or a new abnormality on conventional imaging reports)

F. Dementia

1. The medical record describes a cognitive decline of at least six months and a new diagnosis of dementia in individuals who meet diagnostic criteria for Alzheimer's Disease (AD) and fronto-temporal dementia (FTD)
2. The cognitive impairment is more consistent with FTD (abnormal social interactions, awkwardness, difficulties with speech and language, and decreased abilities for planning and organization) than AD (memory loss)
3. A comprehensive clinical evaluation has been completed by a neurologist (including a history from the patient and family member, a thorough physical exam, a mental status examination, date of symptom onset, review of medication use, neuropsychological testing, and imaging (for example MRI or CT) studies)
4. A SPECT scan to evaluate the condition has not been previously performed

G. Esophageal Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET/CT scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment

3. The PET/CT scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on endoscopy or conventional imaging reports)

H. Ewing's Sarcoma and Osteosarcoma

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

I. Gastric Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

J. Gastrointestinal Stromal Tumor (GIST)

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging, restaging at the completion of anti-neoplastic and/or radiation treatment, or monitoring response to treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

K. Head and Neck Cancer (not including cancers of the central nervous system)

1. The PET scan is ordered for diagnosis, staging, or restaging at the completion of surgical, anti-neoplastic, and/or radiation treatment (the PET for restaging at the completion of treatment should be performed at least twelve weeks after treatment is completed)
2. To identify the site of the primary tumor in an individual with metastatic cervical lymph node(s)

3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

L. Lung Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

M. Lymphoma/Hodgkin's Disease

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is performed for monitoring after a minimum of two cycles of chemotherapy have been completed
4. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

N. Melanoma

1. The PET scan is ordered for diagnosis when metastatic disease has been diagnosed but the primary lesion has not been identified
2. The PET scan is ordered for staging or restaging at the completion of anti-neoplastic and/or radiation treatment when a pathology report confirms the presence of a malignancy
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

O. Merkel Cell Cancer

1. A pathology report confirms the presence of a malignancy

2. The PET scan is ordered for staging to evaluate for metastasis

P. Mesothelioma

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for evaluation prior to treatment

Q. Multiple Myeloma and Plasmacytomas

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging or restaging after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings or a new abnormality on conventional imaging reports)

R. Myocardial Viability

1. The PET scan is ordered to identify individuals with decreased ventricular function (heart muscle movement) that may be candidates for revascularization where the need to differentiate between dysfunctional but viable myocardial tissue and scar tissue is documented
2. The PET scan is ordered in place of, but not in addition to, a single photon emission computed tomography (SPECT) when the PET results will be used to determine myocardial viability prior to revascularization
3. The PET scan is ordered following an inconclusive SPECT scan when the PET results will be used to determine myocardial viability prior to revascularization

S. Neuroendocrine Tumors

1. The PET scan is ordered for diagnosis of a poorly differentiated and unknown primary tumor or staging

T. Occult (Unknown) Cancer

1. The PET scan is ordered for identifying the primary tumor when a pathology report confirms the presence of a malignancy of unknown primary site or the pathology report is inconclusive, a repeat biopsy cannot be performed, and the primary tumor has not been identified on endoscopy, CT, or MRI

U. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for restaging when recurrence is suspected (for example, physical findings, rising tumor markers (an elevation or rise in two consecutive tests performed at least one month apart), or a new abnormality on conventional imaging reports)

V. Pancreatic Cancer

1. The PET scan is ordered for diagnosis or staging of a pancreatic mass on CT or MRI when imaging findings are inconclusive

W. Refractory Seizures

1. The PET scan is ordered for pre-surgical evaluation for the purpose of identifying a focus of refractory seizure activity for individuals with intractable epilepsy

X. Soft Tissue Sarcoma (not including Gastrointestinal Stromal Tumor)

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for staging

Y. Solitary Pulmonary Nodule

1. The PET/CT scan is performed for a newly identified pulmonary nodule found on a chest xray or CT. An individual with multiple pulmonary nodules is not covered under this condition unless a single new pulmonary nodule is identified when compared to prior imaging studies.
2. The pulmonary nodule is at least one centimeter (ten millimeters) in size, but less than four centimeters (forty millimeters) in size

Z. Testicular Cancer

1. A pathology report confirms the presence of a malignancy
2. The PET scan is ordered for restaging when residual tumor or recurrence is suspected (for example, physical findings, persistently elevated or rising tumor markers (an elevation or rise in two consecutive tests (alpha fetoprotein or serum chorionic gonadotropin) performed at least one month apart), or a new abnormality on conventional imaging reports). The

PET should be performed a minimum of six weeks after the completion of treatment.

AA. Thymic Cancer

1. The PET scan is ordered for diagnosis when a thymic malignancy is suspected

BB. Thyroid Cancer

1. A pathology report confirms the presence of a malignancy (follicular, medullary, papillary, Hurthle cell)
2. The PET scan is ordered for staging or restaging follicular, papillary, or Hurthle cell thyroid cancer after the completion of anti-neoplastic and/or radiation treatment
3. The PET scan is ordered for restaging follicular, papillary, or Hurthle cell thyroid cancer when recurrence is suspected, as evidenced by all of the following:
 - a) Negative I131 whole body scan
 - b) The individual was previously treated by thyroidectomy and radioiodine ablation
 - c) Thyroglobulin greater than 2ng/mL after thyrogen stimulation
 - d) An elevated or rising serum thyroglobulin (Tg) greater than 10ng/ml
4. The PET scan is ordered for restaging medullary thyroid cancer as evidenced by an elevated or rising calcitonin and negative standard imaging tests

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

- D. If used in conjunction with a clinical trial, the PET scan is subject to medical necessity review and all other conditions and terms of the policy or health plan.
- E. A PET scan for routine surveillance in an asymptomatic individual without documentation of recurrence (for example, physical findings, lab values, or conventional imaging reports) is not medically necessary.
- F. A PET scan for any of the following conditions is considered investigational as there is insufficient peer-reviewed scientific literature supporting the usefulness and effectiveness of PET scan in individuals with these diagnoses:
- Bladder Cancer
 - Endometrial Cancer
 - Hepatobiliary Cancer (including Gall Bladder Cancer and Cholangiosarcoma)
 - Kidney (Renal) Cancer
 - Leukemia
 - Neurofibromatosis (not a cancer)
 - Paget's Disease (not a cancer)
 - Prostate Cancer
 - Skin Cancer (other than Melanoma or Merkel Cell Cancer)
 - Small Intestine Cancers (other than Gastrointestinal Stromal Tumor)
 - Uterine Cancer
 - Vulvar Cancer

Documentation Required:

- Office Notes
- PET scan report
- Other imaging reports
- Pathology report

Rationale:

PET scan have been advocated for a variety of conditions, including cancer, ischemic heart disease, and neurologic disorders. Literature supporting the use of PET scans for a number of those conditions is available, but several of the proposed uses are not supported. CMS established a national guideline for coverage of PET scans, but over the past several years have approved coverage for several indications that are not supported by the literature. Literature supporting the use of PET scans for limited cardiac and coronary artery conditions has been published by several reviewers. Guidelines for the use of PET scans for evaluating dementia have been established by the American Academy of Neurology. The National Comprehensive Cancer Network has established guidelines for PET scan use for a variety of oncologic conditions. At this time, the wide coverage for PET scans endorsed by CMS is not supported by the literature and peer-reviewed guidelines from specialty organizations.

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Approved by the Medical Director